

SECTION 2 -- SHOWCASE-- Summary Information for 510k

1- Submitted by:

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OCT 21 2008

Official Correspondent:

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- 2- Proprietary Name:** SHOWCASE®
Common/ Usual Name: Soft-copy reading system

Classification:

| | |
|-----------------------------|--|
| Classification Name | Picture Archiving and Communications System (PACS) |
| Device Class | Class II |
| Classification Panel | Radiology |
| CRF Section | CFR 892.2050 |
| Product Code | LLZ |

3- Substantial Equivalence Predicate Devices:

Substantial Equivalence

ShowCase is substantially equivalent to the following devices:

| Predicate Device Name and Manufacturer | 510(k) Number | Clearance Date | Product Code |
|---|---------------|----------------|--------------|
| eFilm™ Workstation with Modules, eFilm Medical Inc. (became Merge eMed, Inc.) | K020995 | 04/12/2002 | LLZ |

| | | | |
|--|---------|------------|-----|
| syngo® Ultrasound Workplace, Siemens Medical Systems USA, Inc. Ultrasound Division | K060992 | 04/28/2006 | LLZ |
| Volcano s5i Family of Imaging Systems, Volcano Corporation | K061215 | 08/10/2006 | LLZ |

5- Device Description

ShowCase is diagnostic quality radiological viewing software. ShowCase can be used to receive, store, display and manipulate medical images and associated clinical data. This device is not intended for diagnosis of lossy compressed images.

6- Software Development

Trillium Technology certifies that ShowCase software is designed, developed, tested and validated according to written procedures. These procedures identify the individuals within the organization responsible for developing and approving products specifications, coding, verification and validation testing. The software developed for this product provides diagnostic quality images and associated information to the intended users.

7- Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Devices

ShowCase®, eFilm® Workstation and syngo® Ultrasound Workplace are all available as "software only" workplaces that run under Microsoft Windows® operating systems on readily available computer hardware. All applications include image and structured report viewing and a set of imaging measurements and manipulation tools. All three are DICOM compliant systems capable of receiving and storing images and moving imaging studies using DICOM Query/Retrieve.

ShowCase includes some of the ultrasound specific functionality of the syngo Ultrasound Workplace including stress echo displays and Doppler measurement tools.

ShowCase is a more basic level product than the predicate devices and has a smaller overall feature set. ShowCase has no advanced diagnostic modules.

The Volcano s5i family of products is a set of intravascular ultrasound acquisition products that have only one feature in common with ShowCase. The s5i acquisition device includes an interactive display of both the radial and longitudinal views of an IVUS image set, with a 360 degree cursor on the radial view that matches it to the

longitudinal view. This is referred to as the In-line Digital Display (ILD). ShowCase also provides the ILD image playback option for intravascular ultrasound pullback image sets.

8- Safety and Effectiveness

General Safety and Effectiveness Concerns:

ShowCase Workstation labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

The hardware components specified (and optionally supplied) are all "off the shelf" computer components.

The device does not contact the patient, nor does it control any life sustaining devices. Thus, the "Level of Concern" for the ShowCase Workstation is "minor".

8- Validation and Effectiveness

Extensive testing of the software package has been performed by programmers, non-programmers and by potential customers.

9- Conclusion as to Substantial Equivalence

ShowCase Workstation has Indications for Use and a Target Population similar to the predicate devices, eFilm Workstation with Modules (K020995) and syngo Ultrasound Workplace (K060992). Any differences between the ShowCase Workstation software and the equivalent devices have no significant influence on safety or effectiveness. Therefore, ShowCase Workstation raises no new issues of safety or effectiveness from its predicate devices.



Sandra Simon
Operations Director / Owner

14 - Oct - 2008
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trillium Technology, Inc.
% Mr. Gary Allsebrook
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OCT 21 2008

Re: K082135
Trade/Device Name: ShowCase®
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 27, 2008
Received: July 29, 2008

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|----------------|----------------------------------|--------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082135

Device Name: ShowCase®

Indications for Use:

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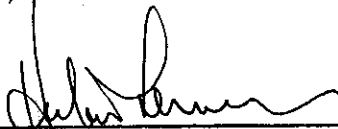
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K082135